

Report on Medicare Compliance Volume 28, Number 5. February 11, 2019

EHR Vendor Settles FCA Case for \$57M; Allegedly Caused Meaningful Use Overpayments

By Nina Youngstrom

As certification problems unfolded at Greenway Health, an electronic health record (EHR) software company, two employees with compliance responsibility talked about the implications for the providers who used its product, Prime Suite, for the EHR incentive payment program. Because Greenway allegedly had fudged its way into EHR meaningful use certification for Prime Suite, providers had unwittingly received money from Medicare and Medicaid under false pretenses.

The employees were worried about inaccurate calculations for the core measure on clinical summaries. “The good news is...it isn’t like it affects health,” one employee, a manager, wrote in an instant messaging program, according to a False Claims Act complaint filed by the Department of Justice (DOJ) against Tampa, Florida-based Greenway. “It just affects \$\$\$.” His colleague agreed. “No patients are jeopardized. Just incentive money.” But he was increasingly uneasy about something else too—the accuracy of user attestation data in the Prime cloud —“because it means that everyday necessitates being shifty and what I ultimately feel is dishonest. Basically for a year I’ve been point man on what slithery options we have forced our users into.”

Hand-wringing aside, Greenway allegedly allowed some providers who used Prime Suite to “submit inaccurate data in connection with applications for federal Meaningful Use funds,” causing them to submit false claims to the government by misrepresenting the capabilities of its software, the complaint alleged. Now Greenway has agreed to pay \$57.25 million to settle the false claims allegations, DOJ and the U.S. Attorney’s Office for the District of Vermont said Feb. 6. DOJ also alleged Greenway gave some users unlawful remuneration to recommend Prime Suite.

Greenway: ‘Products Remain Certified’

In a statement, Greenway said “the settlement is not an admission of wrongdoing by Greenway, and all our products remain [certified by the Office of the National Coordinator for Health Information Technology (ONC)]. This agreement allows us to focus on innovation while collaborating with our customers to improve the delivery of healthcare and the health of our communities.” Greenway entered into a five-year corporate integrity agreement (CIA) as part of the settlement. It requires Greenway to let Prime Suite customers get the newest version free, move their data to another Greenway software product or transfer their data to a different EHR vendor at no charge.

This is the second vendor to pay a whopping fine for selling software for the EHR incentive payment program that doesn’t satisfy ONC requirements for meaningful use of certified EHR technology, which is required for hospitals and physicians to receive incentive payments. eClinicalWorks paid \$155 million in 2017 to settle false claims allegations for misrepresenting its meaningful use of EHRs and causing providers to do the same. For example, the software allegedly did not reliably perform drug interaction and drug allergy checks, according to DOJ and the U.S. Attorney’s Office for the District of Vermont. eClinicalWorks denied the allegations.

Last year, eClinicalWorks also paid a \$132,000 “stipulated penalty” for failing to report certain patient-safety

issues to the HHS Office of Inspector General, as required by its CIA.

To be eligible for meaningful use payments, hospitals and physicians must use EHR software that's certified by independent bodies approved by ONC. Greenway retained the Certification Commission for Health Information Technology (CCHIT) to test and certify Prime Suite. ONC doesn't require testing of everything; "testing takes a snapshot of a product's capabilities by ensuring it can pass certain test cases for which developers are provided the test scripts in advance," the complaint states.

Hospitals Should Ask Vendors About Compliance

DOJ alleged that Prime Suite could not satisfy all requirements for certification "at the time of its testing to the 2014 Edition certification criteria in January and February 2013—and for many years thereafter." So Greenway allegedly misrepresented that it met certification criteria.

For example, Greenway told CCHIT that Prime Suite satisfied e-prescribing requirements, including adopting the RxNorm vocabulary. But that wasn't the case, DOJ alleged. Greenway also "misrepresented that Prime Suite maintained and communicated patients' problem lists using SNOMED-CT codes so that other EHR systems would be able to read and incorporate important patient information," the complaint alleged.

Because the software coding was allegedly "manipulated" to cover up its "failings," Prime Suite passed CCHIT certification and was released, the complaint said. As a result, Greenway's users submitted thousands of Stage 2 claims to Medicare and Medicaid and unknowingly falsely attested that they met meaningful use requirements and were therefore eligible for incentive payments, DOJ alleged.

The settlement, like the eClinicalWorks settlement, is "a cautionary tale" about the risks of moving too fast with technology and other advances, says former federal prosecutor Jason Mehta, with Bradley in Tampa. "Before deploying innovative health strategies, new software, technology or clinical approaches, practitioners need to be mindful that innovation is compliant." When he was a prosecutor, Mehta says the "most egregious cases" involved vendors, clinicians and durable medical equipment companies that rushed to market "without fully vetting products and ensuring they were working appropriately. That's what this case demonstrated. [Greenway] allegedly didn't ensure it complied fully with meaningful use."

There was no qui tam relator behind the Greenway complaint. Both Greenway and eClinicalWorks were pursued by the U.S. attorney's office in Vermont, which left providers out of it. "Time will tell whether the government will be looking at others down the chain. I'm cautiously optimistic that the government will not hold hospitals and users of software accountable for the alleged problems with software," Mehta says. But "the most responsible thing for hospitals and health systems to do to stay out of the government's crosshairs is to install the latest updates" from software vendors. "Ask questions of vendors to make sure they're compliant," Mehta says. "As a clinician, you should document all efforts to ensure you're only using software that's compliant."

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